IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1978

NO. 78-429

WILLIAM and MAXINE HASTE, Petitioners,

v.

AMERICAN HOME PRODUCTS, CORPORATION,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

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OF COUNSEL

COUNSEL FOR PETITIONERS

August 11, 1978

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CITATIONS

CASES:

MISCELLANEOUS:

IN THE

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The Petitioners, William and Maxine Haste, respectfully pray that a Writ of Certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Tenth Circuit entered in this proceeding on June 14, 1978.

OPINION BELOW

The opinion of the Court of Appeals is designated for publication but has not yet been published. The District Court decisions from the District of Wyoming were not published. All opinions appear in the appendix attached hereto.

JURISDICTION

The judgment of the Court of Appeals for the Tenth Circuit was entered on June 14, 1978, reversing the ruling in the Memorandum Opinion of the District Court for the District of Wyoming entered on June 13, 1975, and thereby, the Order on Damages entered by the District Court for the District of Wyoming on August 9, 1976 and the judgment entered on August 11, 1976. Rehearing before the United States Court of Apeals for the Tenth Circuit was denied on July 31, 1978. This petition for a Writ of Certiorari was filed within ninety (90) days of the ruling entered June 14, 1978. This Court's jurisdiction is invoked under 28 U.S.C., §1254(1).

QUESTIONS PRESENTED

1. Whether it is proper for the Tenth Circuit to base its Appellate

decision on a "finding of fact" by the trial judge that Anaplaz is a prescription drug where the trial opinion notes that the judge accepts the argument "albeit the record is short a few elements of proof of a true prescription drug."

2. Whether a prescription drug which was not sold or ordered by a veterinarian as a prescription drug is still entitled to the exemptions under 21 U.S.C. §353(b)(2).

3. Whether the manufacturer of a vaccine for animal use, advertised to the public as "safe" and "incapable of causing disease" and in which advertisements no mention is made of adverse effects, or side effects known to the manufacturer as required by 21 U.S.C. § 352(n) and 21 C.F.R. § 202.1(e), satisfies its duty to warn of dangerous side effects by notifying veterinarians of these adverse effects.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Certain sections of the Food, Drug and Cosmetic Act, Title 21 U.S.C. § 352(f), (n), 21 U.S.C. § 353 (b)(1), (b)(2).

Code of Federal Regulations, Title 21, C.F.R. §202.1(e); 21 C.F.R § 202.1(e)(3); 21 C.F.R. §202.1(e)(3)(iii); 21 C.F.R. § 202.1 (e)(5); 21 C.F.R. § 202.1(e)(6)(i), (iii), (iv), (v), (xviii); 21 C.F.R. § 202.1(e)(7)(i), (vii), (viii), (xi), (xii); 21 C.F.R. §201.105

The text of the above are set out in the Appendix.

STATEMENT OF THE CASE

This case was originally filed in the district of Wyoming under diversity of citizenship where the amount in controversy exceeded Ten Thousand Dollars ($10,000.00) on July 31, 1973. Trial to the Court was bifurcated by Judge Winner, sitting specially in the District of Wyoming, and the issue of liability was decided favorably to petitioners by Judge Winner on June 13, 1975. Trial on the issue of damages was then had and a Memorandum Opinion awarding Forty nine thousand nine hundred ninety seven dollars ($49,997.00) to petitioners was filed on August 9, 1976, and judgment entered thereon on August 11, 1976. The petitioners then appealed the award of damages to the Tenth Circuit Court of Appeals and the defendant filed a Cross

Appeal contending that liability was erroneously imposed. The Court of Appeals, On June 14, 1978, ruled in favor of the Defendant's Cross Appeal finding that liability could not attach.

The Hastes, petitioners here, bought Anaplaz vaccine through their veterinarians beginning in 1971. Anaplaz is a vaccine manufactured by the respondent corporation to prevent Anaplasmosis. During the course of the development of this vaccine, the defendants were warned by the Department of Agriculture and several independent imunogeneticists that the vaccine was a probable cause of a disease known as neonatal isoerythrolysis (NI). This disease causes severe anemic reactions of the calf if it suckles the cow after birth and results in the death of the calf unless it is immediately removed after birth from the dam and nursed artificially while the dam is milked of colostrum.

The Hastes had read about Anaplaz vaccine in advertisements appearing in numerous cattlemen's magazines extolling the virtues of Anaplaz vaccine with language indicating it was "safe", "incapable of causing disease" and that there was no longer a need to run the risks of Anaplasmosis. The Hastes in-

noculated their entire herd of cross bred Santa Gertrudis cattle as instructed by the package insert, giving the final booster shot in January of 1973.

After the final booster in the calving season of 1973, the Haste cows began to drop NI infected calves. During the liability trial, Judge Winner found that thirty two (32) calves died as a result of NI proximately caused by the Anaplaz vaccine. He also found that the petitioners were forced to sell one hundred ninety one (191) cows for slaughter, since they would produce only NI calves in the future due to the Anaplaz innoculations. The entire Santa Gertrudis upgrading program was lost although no award was made for this loss.

Judge Winner decided the liability issue in favor of petitioners, finding that, notwithstanding the fact that Anaplaz might be considered a prescription drug, that it was not sold as one in this case. The warnings given through the Dear Doctor letters to the veterinarians were insufficient to overcome the inducements placed directly to the public through the cattlemen's magazines, and, therefore, that the defendant was negligent in failing to reasonably warn the

the public of the adverse effects of Anaplaz. He further found that there was a breach of the warranties in the advertisements.

At the trial the testimony of Dr. Roberts indicated that he had not, and did not, consider Anaplaz to be a prescription drug. He testified that he ordered it for the Hastes, even though he did not think it was an appropriate treatment. Judge Winner found the warnings given by the veterinarians to the Hastes to be inadequate and minimal. However, in an ambiguous paragraph of his decision appearing on page 42 of the appendix, Judge Winner indicated that he accepted the defendants argument that Anaplaz was a prescription drug "albeit a few elements of proof are missing." The Court of Appeals ruled that the lower court, having "acknowledged" that Anaplaz was a prescription drug, must therefore find the warnings given the veterinarians satisfied any duty to warn, since prescription drugs are excepted from the notice requirements of 21 U.S.C., §352(n) by the "prescription drug doctrine." The issue of the insufficiency of damages was never reached by the Court of Appeals, since it was mooted by their decision on liability.

Petitioners ask for a Writ of Certiorari to review the decision of the Court of Appeals regarding liability Petitioners still assert that the damages awarded were insufficient, and request that this case be sent back to the Tenth Circuit for determination of the sufficience of the damages award. Should the ultimate opinion be favorable to Petitioners.

1. THE DECISION OF THE TENTH CIRCUIT COURT OF APPEALS DEPARTS FROM THE ACCEPTED AND USUAL COURSE OF JUDICIAL PROCEEDINGS IN MAKING A FINDING OF FACT UNPROVEN IN THE RECORD AND UNSUPPORTABLE AS A MATTER OF LAW.

The opinion of the Court of Appeals is based upon a finding that Judge Winner "acknowledged that the drug was a 'prescription drug'" and, therefore, the respondent discharged its duty to warn the Hastes, petitioners here, by the warnings given to veterinarians (App. p. 11). Unfortunately, Judge Winner's opinion does not make a clear finding of fact that Anaplaz was a prescription drug. This is the language upon which the Court of Appeals determines

that the trial Court "acknowledged" Anaplaz to be a prescription drug.

> Moreover, for purposes of resolution of this case, I accept defendants' arguments that Anaplaz and its sale should be treated as the sale of a prescription drug, albeit the record is short a few elements of proof of a true prescription drug. (App. 42)

The trial opinion read as a whole was to the effect that even if Anaplaz were a prescription drug it was knowingly not sold as a prescription drug and, therefore, the warnings given must be reasonably calculated to reach and adequately inform the public. Judge Winner's "acceptance" of the defendant's argument was not a finding of fact and should not be sanctioned as one on the basis of the record and law. Argument is not evidence.

Procedurally, the burden placed upon the Petitioners in this situation is untenable. At the trial the burden of proof of an affirmative defense rests on the defendant. At the trial no substantial evidence of any sort was presented to prove that Anaplaz was considered a prescription drug. The Court of Appeals

has raised argument above proof.

Judge Winner found that Anaplaz was not sold as a prescription drug and that the respondent was well aware of that fact. (See App. p. 53) The trial testimony from the veterinarian who originally ordered the Anaplaz, Dr. Roberts, was that he did not order the Anaplaz through a prescription as he did not believe it was a prescription drug. Furthermore, prescription drugs are defined under 21 U.S.C. §353(b)(1) as drugs "for use by man." (see App. p. 70). Anaplaz was never intended to be a human vaccine. Animal drugs can be required to be sold pursuant to prescription if they fall within the descriptive criteria set out in 21 C.F.R. §201.105 (See App. p.85) No evidence that those criteria were applicable to Anaplaz was presented at trial. (Such a prescription only exempts the manufacturer from compliance with 21 U.S.C. §352(f) related to listing directions for use and not from the advertising requirements of 21 U.S.C. §352(n), however.) Furthermore, individuals are normally presumed to have acted within the law and if Anaplaz were a prescription drug, then the advertisements admitted into evidence and mentioned in the trial Court (App. pp. 35, 37, 38) and Appellate decisions (App. 7) would have

been in violation of the "brief summary" requirements of 21 C.F.R. §202.1(e), 21 C.F.R. § 202.1(e)(3), 21 C.F.R. § 202.1(e)(3)(iii), 21 C.F.R. §202.1(e)(5) and 21 C.F.R. §202.1(e)(6). (See Appendix beginning p. 72) The Court of Appeals decision agrees that the advertising was laudatory and contained no warnings whatsoever regarding the Department of Agriculture statement, potential danger or the results of any of the testing indicating NI side effects known by the respondent prior to its advertising campaing. Only if Anaplaz were not a prescription drug would the respondents be acting within the requirements of the regulations.

The trial Court's decision readily admits that proof was lacking and the law itself indicates that veterinary drugs in general are not "prescription drugs". The court of Appeals has erroneously raised an "assumption for purposes of argument" to the level of a "finding of fact." This interpretation of Judge Winner's opinion requires that petitioner's appeal a favorable ruling, based upon what appears to be sound legal analysis, in order to protect against appelate disapproval of the legal reasoning and construction of the ambiguous "acceptance" as a "finding of fact." It ignores the

necessity of evidentiary proof and by implication creates a veterinary "prescription drug" in contradiction to statute and code section.

The opinion of the Tenth Circuit creates an unsupportable finding of fact from a small part of Judge Winner's decision. It has denied the Petitioners a fair and impartial determination of the facts in their case. This Court should grant Certiorari to review the unusual procedure and the factual determination made by the Appelate Court.

2. THE DECISION OF THE TENTH CIRCUIT IS IN CONFLICT WITH THE DECISIONS OF OTHER CIRCUITS AND 21 U.S.C. §353(b)(2) IN THAT IT EXTENDS THE PRESCRIPTION DRUG DOCTRINE TO SITUATIONS WHERE THE DRUG IS NOT DISPENSED THROUGH A PRESCRIPTION.

The Tenth Circuit decision creates a far more liberal "prescription drug doctrine" than is described in 21 U.S.C. § 353(b)(2) (see App. p.71) or applied in the Ninth and Fifth Circuits. See Davis v. Wyeth Laboratories, 399 F2d 121 (9th Cir. 1968) and Reyes v. Wyeth Laboratories, 498 F2d 1264 (5th Cir. 1974).

This new doctrine is based upon what the Tenth Circuit terms a "typical" prescription drug sale. (See App. p.12) Judge Winner's trial opinion found that the sale of Anaplaz, even if it were a prescription drug, was certainly not "typical" in view of the direct advertising campaign. (See App. pp.42, 44, 45)

The Hastes wer e in uced to purchase Anaplaz by a substantial sales promotion directed to the lay public and evidenced by advertisements in over forty cattlemen's magazines. No mention of contraindications, adverse effects or risks was made in the laudatory descriptions of the benefits of using Anaplaz in these advertisements. (See Apellate Dec. App. pp. 6 & 7 and Trial Opinion, App. p.p. 35, 38) If Anaplaz were a prescription drug then it was not advertised as one as required by the regulations regarding a fair presentation in brief summary in all advertisements of prescription drugs of known adverse effects, contraindications or other risks of use. (See 21 C.F.R. § 202.1(e) et seq. at App. p. 72) In none of the "prescription drug doctrine" cases cited by the Court of Appeals was direct advertising, not in compliance with the regulations, employed by the manufacturer to induce consumers to order the product. (See Appellate Dec app. p. 13)

While Judge Winner did not mention the trial testimony of Dr. Roberts in his opinion it obviously played a part in his determination of this case. It appears in the appendix filed in the Court of Appeals beginning at page 126 and reads as follows.

DR. ROBERTS: The first Anaplaz vaccine that they purchased from me was picked up and charged to them on November 20, 1971.

MR. HIRST: That was the other occasion you talked to them about it?

A.. Yes, sir.

THE COURT: Was a prescription given for this vaccine on that day by you? Did you write a prescription for it?

THE WITNESS: No. It is not required to write a prescription for it.

MR. HIRST: What the Judge wants to know is: How did you get the vaccine?

THE WITNESS: Ordered it from Fort

Dodge.

THE WITNESS: I have copies here of the invoices.

MR. HIRST: If the Court please: May I approach the bench?

THE COURT: Yes. I just wanted to be sure that he didn't regard it as a prescription drug.

MR. HIRST: That he what?

THE COURT: That he does not regard it as a prescription drug. And I gather you do not, is that right?

THE WITNESS: It is for --

THE COURT: Do you feel the drug can be sold by you as a licensed veterinarian without having you write a prescription for it, or do you feel that you must write a prescription for it? All I want to know is your view in the matter.

THE WITNESS: No, I don't feel that I have to write a prescription

to sell this product.

In cases where drugs, denominated as prescription drugs, are not sold as presciption drugs the Ninth and Fifth Circuits have ruled that the manufacturer must provide the ultimate consumer with adequate information so that he may make an informed decision as to whether to use the drug or not.

In a polio vaccine case where the manufacturer was held liable for the polio contracted by the plaintiff, the Ninth Circuit Court of Appeals stated:

> Here, however, although the drug was denominated a prescription drug, it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved. In such cases (as in the case of over-the-counter sales of nonpre- scription drugs) warning by the manufacturer to its immediate purchaser will not suffice...in such cases, it is the responsibil- ity of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning. Davis v Wyeth

Laboratories, 399 F.2d 121 (9th Cir.1968)

While the facts of the Davis case are distinguishable from those here, the policy is the same. If the drug is not dispensed by filling or refilling a prescription, warning must be given to the consumer directly by the most reasonable means available to adequately inform the user of the risks.

It is apparent that the trial court found that Anaplaz was not sold as a prescription drug and that the defendant was well aware of that fact. (See, Trial Opinion, App. pp. 35, 42, 44, 53) In a Fifth Circuit case involving the Sabin oral polio vaccine which, though denominated a prescription drug, was not dispensed as one the Court stated:

> Thus, as in the case of patent drugs sold over the counter without prescription, the manufacturer of a prescription drug who knows or has reson to know that it will not be dispensed as such a drug must provide the consumer with adequate information so that he can balance the risks and benefits of a given medication himself. (emphsasis added.) Reyes v. Wyeth Laboratories

498 F.2d 1264 (5th Cir. 1974).

The Appellate Court as well as the Trial Court in this case recognized that the warnings given to the Hastes were inadequate and minimal. Certainly, they were insufficient to allow them to balance the risks and benefits of a given medication. (See Appellate Opinion App. 11; Trial Opinion App. pp.38, 39, 65.)

Judge Winner's trial opinion specifically finds that the

> ...defendant knew or had reason to know that Anaplaz would not be administered as a prescription drug. It had a duty to warn foreseeable users, and that duty was for a clear,explicit warning in the solicitations leading to the sale-not in a package insert after the solicited sale had been accomplished. (See Trial Court Memorandum, App. pp. 53-54.)

The statutory codification of the "prescription drug doctrine" is found under 21 U.S.C., §353 (b)(2), which exempts any drug from, among other things, certain requirements of warning in advertising that are required by 21 U.S.C.

§ 352(n) if the drug is "dispensed by filling or refilling a written or oral prescription of a practitioner..." (See Appendix pp.70 & 68) Since Dr. Roberts did not order Anaplaz pursuant to a prescription the doctrine should not apply. However the Court of Appeals held that:

> The trial court was in error in holding that the contents of the advertisements of Anaplaz in the various livestock publications are controlling on the warning issue, and thus override the practical considerations which arise from the requirement that the consumer purchase the vaccine only from veterinarians, and override the established 'prescription drug' doctrine. Court of Appeals Decision Appendix p.p. 11-12)

This language extends the "prescription drug doctrine" to situations where the lay consumer determines what medication he needs based upon the insufficient and false information supplied in advertisements and then seeks out a practitioner who will consent to order the drug requested without prescribing it. Normally a patient can make a determination of whether to follow the practitioner's

advice. It is not "typical" to tell the practitioner what the medication should be and then order it from him. The decision of the Court of Appeals ignores the realities of veterinary drug marketing. The drugs are sold through veterinarians, not druggists at the corner pharmacy. Judge Winner found that Dr. Roberts received a "tidy profit" from the sale of the Anaplaz to the Hastes. (See App. p. 38). The normal sale of a prescription drug does not, and should not, result in a profit to the prescribing physician.

The prescription drug doctrine was developed since the practioner would normally be the person who assess the medical risks of the use of a drug in light of the expert knowledge he has of the values and drawbacks in a certain situation. In such cases, where the practitioner makes the initial choice as to whether to use or not to use a drug, reasonable notification to the practitioner of side effects and risks is sufficient to protect the public. A "prescription" implies an expert determination of the efficacy and need of a particular patient for a particular medication. Where no prescription is used to order a drug then the manufacturer has a duty to reasonably notify the

user of known risks since the anticipated professional intervention is eroded. (see Singer v. Sterling Drug,Inc., 461 F.2d 288 (7th Cir. 1972); Davis v. Wyeth Laboratories, 399 F.2d 121 (9th Cir. 1968) Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir 1974.)

In view of the fact that Anaplaz was not sold as a prescription drug, the "prescription drug doctrine" should not apply to protect the manufacturer. This case should be reviewed to prevent a misinterpretatin of 21 U.S.C. § 353(b)(2) and to prevent a conflict with the policies and decisions of other circuits.

3. THE DECISION OF THE TENTH CIRCUIT IS IN CONFLICT WITH THE DECISION OF OTHER CIRCUITS AND STATE COURTS IN EVALUATING WHAT CONSTITUTES REASONABLE WARNING OF KNOWN RISKS WHERE ADVERTISING IS DIRECTED TO THE PUBLIC.

The Food, Drug and Cosmetic Act 352(n) and the regulations under 21 C.F.R. § 202.1(e) require that manufacturers include certain minimal truths related to side effects in their advertising. These requirements are essential to protect the public from

exactly the situation that occurred in this case. The decision of the Tenth Circuit condones the manufacturer's practice of false or insufficient advertising to the lay public, avoiding any mention of risks in contravention of the regulatory requirements, and places the burden on the practitioner to correct the falsehoods and fraudulent statements made in the advertisements. This cannot be a proper result. (See Appendix starting p.72.)

Reasonable warning under the circumstances of the individual case has been a requirement of the "prescription drug doctrine". In Love v. Wolfe, 58 Cal. Rep. 42(4d Dist. Ct. of Appeals 1967), the California Court of Appeals noted that failure to warn and over promotion were factual questions to be submitted to the jury with the following language:

> Action designed to stimulate the use of a potentially dangerous product must be considered in testing the adequacy of a warning as to when and how the product should not be used. (emphasis added) Love v. Wolfe, 58 Cal. Rep.at 220.

Other cases indicate that the custom and practice of a manufacturer in "over--

promoting" its product must be considered in testing the reasonableness of a warning in view of the circumstances surrounding the sale of a product. See Incollingo v. Ewing, 444 Pa. 263, 283 A.2d 206 (S.Ct. of Pa. 1971) and Stevens v. Park Davis & Co., 107 Cal. Rep. 45, 507 P.2d 653 (S.Ct. 1973).

Judge Winner correctly cited and followed Sterling Drug v. Yarrow, 408 F.2d 978 (8th Cir. 1969) for the proposition that a warning must be reasonable under the circumstances,

> We conclude that where a drug is manufactured without negligence but is unreasonably dangerous if a reasonable warning of a side effect is not given, that the manufacturer may be held liable for the injury resulting from the failure to give a warning reasonable under the circumstances. (emphasis added) (Sterling Drug v. Yarrow, 408 F.2d at 993)

Judge Winner's decision follows the "over-promotion" line of cases and requires reasonableness of the warning in the following language of his opinion:

I think that based on the state of scientific knowledge when plaintiffs purchased the Anaplaz, and had plaintiffs not been presold on its use by the advertising literature, the warning is borderline, but it might be sufficient. ... The "Dear Doctor" letters played down the relationship between Anaplaz and NI, and the literature and most particularly the package inserts say that, "evidence suggests a breeding disposition exists with 75% of the known cases existing in Charolais or Charolais crosses." (Plaintiffs were raising Santa Gertrudis). At best, the package insert warning is skimpy even for a drug sold as a true prescription drug not advertised directly to the public. With the sales job the defendant did on the cattlemen who were the ultimate purchasers, the warning is entirely inadequate, and the defendant is liable for failure to adequately warn of the danger of NI. ... I think that the direct sales effort (even though the product was channeled through veterinarians) imposed on defendant a duty to warn the ultimate consumer be- fore he spent his money on the purchase. Defendant's duty was to warn fully

and fairly of risks likely to be encountered as shown by all of the scientific knowledge - not just that shown by knowledge culled, slanted and carefully selected by defendant. (Trial Memorandum App. pp. 42-43,44.)

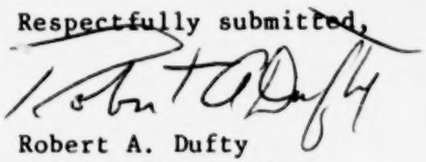
The Tenth Circuit decision invokes the "prescription drug doctrine" to protect the manufacturer of a veterinary product which is advertised directly to the public as "safe" and "incapable of causing disease" from any liability when disease results. Under the facts, even as set out by the Tenth Circuit, a manufacturer is free to publish lies to the public and protect itself from liability by sending "Dear Doctor" letters to veterinarians.

In view of the statutory and regulatory requirements of truth in the advertising as well as revelation of known side effects and the case law relating to reasonableness and adequacy of warning under the circumstances of the individual case the Tenth Circuit Court of Appeals' decision should be reviewed to adequately consider the question of what constitutes a reasonable warning in situations where there is direct advertising to the public.

CONCLUSION

The decision of the Court of Appeals should be reviewed by this Court to correct an unusual and improper "finding of fact" on the part of the Tenth Circuit Court of Appeals. Furthermore, the Court of Appeals decision should be reviewed to clarify the parameters of the "prescription drug doctrine' when advertising is channeled directly to the public related to the sale of potentially dangerous drugs. Without clarifications from the Supreme Court, the decisions of the circuits will be in conflict and the statutory language will be clouded.

Respectfully submitted,



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Counsel for Petitioner

September 8, 1978

APPENDIX

AUGUST TERM - AUGUST 14, 1978

Before Honorable Oliver Seth,
Honorable Robert H. McWilliams,
Honorable James K. Logan,
Circuit Judges.

NO. 76-2015

WILLIAM HASTE and MAXINE HASTE,

Plaintiffs-Appellants,

vs.

AMERICAN HOME PRODUCTS CORPORATION,

Defendant-Appellee.

This matter comes on for consideration of appellants' motion for stay of mandate in the captioned cause pending application to the Supreme Court for certiorari.

Upon consideration whereof, it is ordered that the mandate shall be stayed until September 13, 1978, pending certiorari

and that if on or before that date there is filed with the Clerk of the Court of Appeals a notice from the Clerk of the Supreme Court of the United States that appellants have timely filed a petition for writ of certiorari in the Supreme Court, the stay shall continue until final disposition by the Supreme Court.

Howard K. Phillips, Clerk

MAY TERM - JULY 31, 1978

Before Honorable Oliver Seth, Chief Judge
Honorable William J. Holloway, Jr., Circuit Judge
Honorable Robert H. McWilliams, Circuit Judge
Honorable James E. Barrett, Circuit Judge
Honorable William E. Doyle, Circuit Judge
Honorable Monroe G. McKay, Circuit Judge
Honorable James K. Logan, Circuit Judge

WILLIAM HASTE and MAXINE HASTE, Plaintiffs-Appellants and Cross-Appellees,	No. 76-2015
vs.	
AMERICAN HOME PRODUCTS CORPORATION, Defendant-Appellee and Cross Appellant.	No. 76-2016

This matter comes on for consideration of the petition for rehearing with suggestion for rehearing en banc filed by appellants and cross-appellees, William Haste and Maxine Haste.

Upon consideration whereof, the petition for rehearing is denied by Chief Judge Seth, and Circuit Judges McWilliams and Logan.

The petition for rehearing having been denied by the panel to whom the case was argued and submitted, and no member of the panel nor judge in regular active service on the Court having requested that the Court be polled on rehearing en banc, Rule 35, Federal Rules of Appellate Procedure, the petition for rehearing is denied.

Howard K. Phillips, Clerk

PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

Nos. 76-2015-16

WILLIAM HASTE and MAXINE HASTE,	)
Plaintiffs, Appellants, and Cross-Appelles,	)Appeal From)The United)States
v.	)District)Court For
AMERICAN HOME PRODUCTS CORPORATION,	)The)District of)Wyoming
Defendant, Appellee, and Cross-Appellant.	)(D.C.#Civil)5899)

Pamela N. Hultin, of Bader & Dufty, Denver, Colorado, for Appellants.

Glenn Parker, of Hirst & Applegate,

Cheyenne, Wyoming for Appellee.

Before SETH, Chief Judge,McWILLIAMS and LOGAN, Circuit Judges.

SETH, Chief Judge.

This is a products liability case on appeal from a judgment after trial without a jury in which the defendant-appellee, American Home Products Corporation, a manufacturer of an animal vaccine called Anaplaz, was held liable to plaintiffs-appellants, William and Maxine Haste. The plaintiffs appeal an award of $49,997.00 as inadequate damages. The defendant-cross-appellant maintains that no substantial evidence of causation was presented, and improper standards were applied in determining liability.

Mr. & Mrs. Haste are experienced cattle ranchers in Park County, Wyoming, in the business of breeding cattle. It was their intention to upgrade their herd by eventually producing a purebred, top quality herd of Santa Gertrudis cattle.

In an effort to so upgrade the herd, they purchased a number of cattle which they later found to have a disease called anaplasmosis.

The defendant is a manufacturer of the vaccine Anaplaz. It was through the defendant's advertising that the plaintiffs first learned of Anaplaz as a possible means to control anaplasmosis. As a result of the loss of a number of cattle from anaplasmosis, the plaintiffs discussed the use of Anaplaz with their veterinarians as a means to prevent any further outbreaks of the disease. The interest in Anaplaz was prompted, according to Mr. Haste's testimony, because it had been advertised in livestock magazines as the only safe and economic measure available to assist a rancher in preventing anaplasmosis. The advertising campaign for Anaplaz was both extensive and self-laudatory.

In 1970, American Home Products was aware of possible side effects the use of Anaplaz might have on newborn calves. A release by the United States Department of Agriculture on December 29, 1969, makes clear that there was at least some uncertainty as to the hazardous nature of Anaplaz. It said in part: "Vaccinating brood cows with anaplasmosis vaccine

sometimes may cause fatal side effects in calves."

The dispute arises over the asserted duty of defendant to reasonably inform the public of the possibly dangerous side effects the administration of Anaplaz might have on cattle. The evidence shows instances where package inserts for Anaplaz were amended to include a warning of a possibility of neonatal isoerythrolysis (NI) in calves through the use of Anaplaz, and a notice that it could be used only on order of a licensed veterin arian. Letters were also sent to veterinarians in effect informing them of the risk of NI. The advertising material, however, did not notify the ultimate purchaser of any risk. In fact, certain advertisements made the following statements:

> "Vaccination with Anaplaz has met trial by fire in five years of field use. . . with a coordinated effort, a successful breakthrough was finally made, resulting in a safe, practical and effective vaccine. . . five years of Anaplaz field use has shown there's no longer any reason for running the risks of suffering the ravages of anaplasmosis."

Defendant points out that there was at least one instance of NI in plaintiffs' cattle which had not been vaccinated with Anaplaz. The trial court, however, found that thirty-one calves were lost as a proximate result of the Anaplaz vaccination. Damages were also awarded for the diminution in value of 151 brood cows. Plaintiffs-appellants request this court to order either additur, or remand to the trial court to redetermine the amount of damages as to the remainder of the unaccounted-for brood cows. They also argue that damages for the upgrading program should not have been excluded because evidence was presented that except for the incidence of NI, plaintiffs would have been capable of producing a herd of purebred Santa Gertrudis cattle suitable for sale as breeders.

The trial judge based his conclusions as to liability on the degree to which defendant misrepresented, in ads directed to cattle ranchers, its knowledge of the hazardous side effects the vaccine might have on newborn calves. As pointed out by the trial court, in Maxted v. Pacific Car & Foundry Co., 527 P.2d 832 (Wyo.), the Wyoming Supreme Court refused to apply strict liability in a products liability case. Bruce v. Martin-Marietta Corp., 544 F.2d 442 (10th Cir.); Colorado Serum Co., v. Arp, 504 P.2d 801 (Wyo.).

The basic question on appeal is the

extent and nature of the required warning to be given by Defendant. The trial judge acknowledged that the drug was a "prescription drug." The Anaplaz vaccine was only available from veterinarians, and plaintiffs obtained the dosages here concered from their veterinarians. In this aspect of the case, it makes no difference whether the drug was compounded by the defendant or by a pharmacist. Since it is a prescription drug, the doctrines applicable thereto must be applied, and the trial court was in error in not so doing.

The record establishes that the maker of the vaccine had warned the veterinarians of the NI danger by what are referred to as "Dear Doctor" letters. The veterinarians apparently were also aware of such possible side effects from other sources. The containers for the vaccine had a clear warning in red to read the circular enclosed in the package. This warning on the outside said in part: "Do not use until isert leaflet has been read, understood and explained to the owner." This enclosed leaflet, in turn, stated clearly that it had been reported that the use of Anaplaz may be associated with the occurence of NI. It also said, "Field Evidence suggests the vaccination of brood cows with Anaplaz can be a calculated risk and the protective benefits of vaccination should be weighed against the possible risk of neonatal isoerythrolysis."

The warnings to the veterinarians by the defendant were established, and were adequate under the prescription drug doctrines.

The trial court in its memorandum said:

> "With their cattle having anaplasmosis, and having become interested in Anaplaz through defendant's advertising, in the spring of 1971, plaintiffs consulted Dr. Virgil Humphreys, a veterinarian in Worland, Wyoming, and they asked him about Anaplaz."

Dr. Humphreys, according to the trial court's memorandum, gave minimal warnings as to the risks, and recommended the use of Anaplaz. He told plaintiffs that he had used it on his own livestock. The plaintiffs did not buy any vaccine then. They testified, however, that they relied on the advice of Dr. Humphreys.

Some time later, in October of 1971, plaintiffs went to the veterinarian, Dr. Roberts, another of their "regular" veterinarians. They apparently talked with him some two hours. He did not recommend the use of Anaplaz. They visited him a second time. The trial judge found no adequate warning by Dr. Roberts directly relating to NI. Dr. Roberts, according to plaintiffs' brief, ". . . testified for the Defendant and he indicated that he would not recommend Anaplaz because of the

danger of N.I. caused by the vaccine." Apparently on the second visit to Dr. Roberts, they told him in substance that they would rely on Dr. Humphreys' "faith in the vaccine", and wanted it. Mrs. Haste testified that Dr. Roberts had said that if it were "he," he would not use the vaccine. Mr.Haste testified he had read the leaflet in the box of vaccine and understood it. This was the vaccine they had Dr. Roberts order for them apparently on their second visit with him.

The plaintiffs also went to a third veterinarian, Dr. Lester, and purchased from him booster shots in January of 1973.

The trial judge considered and evaluated the warnings given plaintiffs by the veterinarians, and found them minimal. However, the record shows that the veterinarians were well aware of the risks. They had adequate advice as to the risks from the defendant. These were the "warnings" which are the significant ones for prescription drugs, and thus controlling here. There were no fact questions as to these warnings.

The trial court was in error in holding that the contents of the advertisements of Anaplaz in the various livestock publications are controlling on the warning issue, and thus override the practical considerations which arise from the requirement that the consumer

purchase the vaccine only from veterinarians, and override the established "prescription drug" doctrines.

The record shows the typical "prescription drug" sequence of events: The Hastes had livestock exposed to anaplasmosis from new stock they had brought into the herd; they became interested in Anaplaz from the ads in the livestock magazines; they consulted their "regular" veterinarians (two of them) before making a decision as to what to do; they received typical medical advice; they balanced the risks; they decided to have the Anaplaz ordered by Dr. Roberts (a veterinarian was the only source); they received it from him; they read and understood the leaflets, and used it. Their veterinarians were knowledgeable on the problem, and were well advised by defendant as to the risks. In this chain or sequence of events, the defendant discharged its duty to plaintiffs by the warnings to the veterinarians.

The oral polio vaccine cases against Wyeth, Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir.), and Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir.), are not contrary to the conclusion here reached. They concern prescription drugs where a warning to the doctor is usually sufficient, but they also concern situations where the drug was administered to large groups, and the indi-

vidual had no contact with a doctor whatsoever. There the courts held in substance that the warning on the label must be sufficient to discharge the maker's duty. Instead this situation is determined by such cases as Johnston v. Upjohn Co., 442 S.W.2d 93 (Mo.); Stevens v. Parke, Davis & Co., 507 P.2d 653 (Cal.), and Mulder v. Parke Davis & Co., 181 N.W. 2d 882 (Minn.). We have instead of the polio cases a direct "patient" doctor consultation and advice as to a prescription drug.

The judgment appealed from by defendant must be, and is, set aside with directions to enter judgment for defendants.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF WYOMING

-o-

WILLIAM HASTE and MAXINE HASTE, Plaintiffs,	)	No. 5899 Civil
vs.	)	
AMERICAN HOME PRODUCTS CORPORATION, Defendant.	)	

JUDGMENT

The above-entitled cause having been tried to the Court, and the court having duly rendered its Memorandum Opinion, and pursuant to such opinion and to the provisions of Rule 58 of the Federal Rules of Civil Procedure, NOW THEREFORE IT IS

ORDERED AND ADJUDGED that the plaintiffs recover of and from the defendant the sum of $49,997.00, together with interest as provided by law; it is

FURTHER ORDERED that the plaintiff have

its costs of action expended herein, to be taxed by the clerk.

Dated this 11th day of August, 1976.

A. Marvin Helart
Clerk, U.S. District Court

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF WYOMING

Civil Action No. 5899

WILLIAM HASTE and MAXINE HASTE, Plaintiffs,	)	
vs.	)	MEMORANDUM OPINION
AMERICAN HOME PRODUCTS CORPORATION, Defendant.	)	

The liability trial in this case presented problems galore, but the headaches which arose in the damage trial are far more difficult. The chief problems stem from the fact that manifestly plaintiffs were hurt, but, except for the stipulated damages, how much they were hurt is difficult to dig out of the contradictory record. Wyoming law is clear that plaintiffs must prove their damage to a reasonable degree of certainty. Reeder Flying Service v. Crompton, (1970) 470 P.2d 281. With equal clarity, it is settled that damages cannot be awarded on the basis of sympathy, although everyone admits that plaintiffs are deserving of sympathy. I cautioned

counsel at the time of trial that plaintiffs were required to prove their damages, and as the case progressed, plaintiffs' damage theories twisted and turned, but finally plaintiffs affirmed that they relied on Exhibits 124 and 125. Plaintiffs' post trial brief seems to me to retreat from this statement made during trial, but nevertheless, I try to make findings as to all of the damage contentions on the record made.

The only easy amounts are those which were stipulated, and I at once get them out of the way and find that plaintiffs are entitled to recover the stipulated amounts:

Costs of vaccine	$1,511.00
Supplies and Vet fees	2,000.00
Extra outside labor	459.00
Extra Haste labor	1,326.00
	$5,296.00

Undoubtedly, plaintiffs are entitled to recover for the cows and calves proven to have been injured or to have died as a result of the use of defendant's product. The legal principle is simple and well established, but the trouble comes with the proof or lack thereof as to how many animals were injured and how many died as a proximate result of the vaccinations. Plaintiffs' testimony at various stages of the proceedings is internally conflicting, and, although plaintiffs

have testified that the herd record books are complete and accurate, their dmage testimony doesn't tie to the record books. Animals which died from the vaccinations must be valued as of the date of death; damages for animals injured have to be awarded on a value before and a value after basis. "After" means value immediately after the injury; not years later. These principles are well settled, and they are damage principles applied in Wyoming. Meredith GMC, Inc., v. Garner, (Wyo.) 328 P.2d 371. The testimony as to the value of the dead cows is all over the lot, and there really isn't any credible evidence of a before and after value. Indeed, it is difficult to figure out how anyone could testify knowledgeably to values such as this. I recognize and sympathize with the problems of proof faced by plaintiffs, but I agree with defendant's position stated in its post-trial brief:

> "In considering the damage to the cows vaccinated and later in considering allowable damages for N.I. calves, an election must be made. Plaintiffs can't recover damages both for damage to cows because they might or do have N.I. calves and also recover for the 1974 and 1975 N.I. calves from such damaged cows. They must take the difference in before and after the value of the cows in 1973, plus the value of the

calves lost in 1973, plus the value of their own 1973 extra labor but no loss after 1973 for their own labor and N.I. calves; OR

"They alternatively can recover the proven value of all of their own extra labor plus the value of all N.I. calves lost whenever lost and they must forego claiming duplicate damages for permanent damage to the cows."

Plaintiffs' penchant for asking double and triple damages isn't limited to claims for damage to the herd. They want cumulative payments for, (a) the extra labor of Haste and his wife in caring for the sick calves, (b) the cost of labor hired to do work Haste couldn't do because he was caring for the sick calves, (c) the value of the crop which allegedly wasn't grown because plaintiff was busy with the sick calves, (d) and the alleged loss of income from custom work which couldn't be performed because plaintiff was taking care of the calves. Sympathy doesn't permit stacking damages this way.

The damage problem is not simplified by the fact that most of the allegedly injured animals were not sold within a reasonable time after the vaccinations when a sale would, of course, give me a shot at finding a correct before and after value. Instead, plaintiffs

want damages for what they say [but have failed to prove] is the lessened value of future calves born to the retained cows, and the lessened value of the cows later sold, albeit much of those lessened values resulted from market fluctuations. Again, as I see it, plaintiffs want to improperly magnify damages, and they want damages not allowed by the law.

There are conflicts throughout the testimony, and, having expressed my thoughts as to damage theories, I find:

The total Haste herd in question was 207 animals, 191 of which were sold and 16 of which were retained. Plaintiffs presented valuation testimony by Mrs. Kimball and plaintiff. Defendants relied on Dr. Lloyd, Bean and Charlesworth and on the actual records. Value at the time of loss and not at some prior or later time is controlling. Rocky Mountain Packing Co. v. Branney, (Wyo.) 393 P.2d 131. Applying this rule, I find that the amount of damages to the brood cows of the Haste herd was:

73 cows suffered a diminution in value of $100	$7,300.00
29 cows suffered a diminution in value of $125	3,625.00
40 cows suffered a diminution in value of $150	6,000.00
9 cows suffered a diminution in value of $200	1,800.00
	$18,725.00

Defendant argues that because there is no known market for new born calves, there can be no recovery. There isn't a very active market for bridges either, but if someone's bridge is destroyed due to negligence, the wrongdoer isn't home free because of the lack of a market. I reject defendant's argument that plaintiff's can't recover for the calves because there isn't an active market for new born animals. The lack of a market doesn't prevent the award of damages, but it surely doesn't help in calculating an amount which is fair. Once more, there is a tremendous spread in the testimony, and I am sure that all a court can do is try to reach a rough approximation of justice. I find that 31 calves were lost as a proximate result of the vaccinations and that:

5 calves were worth $250 each	$1,250.00
12 calves were worth $400 each	4,800.00
13 calves were worth $700 each	9,100.00
1 calf was worth $900	900.00
	$16,050.00

Plaintiffs are entitled to recover for their extra labor, but, as I have mentioned, they are only entitled to recover once, and I reject all claims for loss of crop, purchase of feed and loss of custom work. These claims duplicate the claim for extra work; they are speculative and they were not proven. It is

understandable that there are no records of the long hours spent under emergency conditions, and I am sure that it is difficult for anyone to understand why there can be no recovery for emotional trauma and mental suffering. I am not sure that the law is right in refusing consideration of these damage factors where the damage is to property instead of to the person, but that is the law and I cannot change it. Any awared I make for extra labor is one based largely on judgment rather than on clear evidence which I can analyze. I have searched the record in an effort to be more precise, but precision isn't there. I find that the reasonable value of the extra work plaintiffs were required to perform was $5,000.00. Defendant argues that if plaintiffs are awarded permanent damage to their herd [and they have been] they are not entitled to recover for any extra labor performed during 1974. I understand the reasoning behind this argument, but I do not accept it. The extra labor was performed as a proximate result of the defendant's wrong, and to say that because plaintiffs tried to salvage their herd they shouldn't be paid for the extra work required of them strikes me as sophistry.

There are no other Santa Gertrudis cattle in Wyoming, and plaintiffs are entitled to recover transportation charges. The amount of these is not in serious dispute, and I find

transportation charges to which plaintiffs are entitled amount to $3,676.00.

Plaintiffs are also entitled to reasonable travel expenses incurred or which would be incurred in replacing the lost or damaged animals. Records of such costs are missing. Defendant has estimated that $1,115.00 is a reasonable amount, and it probably is. I round this to $1,250.00, and allow this amount as part of the damage to the herd.

Plaintiffs urge that an allowance should be made for a loss in the overall value of the herd due to interruption in the upgrading program. There are two answers to this contention. The first is that the proof of loss in value was just too skimpy to permit an award. The second is that damage theory assumes a financial ability to immediately replace. Here, the plaintiffs did not have those means, but under the law as I understand it, I am required to assume that they did. For both of these reasons, I award no damages for the loss, if any, to the upgrading program. In summary, then, I find and conclude that plaintiffs are entitled to recover from defendant:

The amounts stipulated to by the parties	$ 5,296.00
Diminution in the value of the herd	18,725.00

Value of the calves	16,050.00
Value of extra labor	5,000.00
Travel expenses	1,250.00
Freight	3,676.00
	$49,997.00

In accordance with the provisions of Rule 58, the Clerk shall forthwith enter judgment in favor of plaintiffs and against defendants for $49,997.00, together with interest and costs as provided by law.

Dated this 9th day of August, 1976.

Fred M. Winner
United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF WYOMING

WILLIAM HASTE and MAXINE HASTE,	]	
Plaintiffs,	]	CIVIL ACTION
vs.	]	NO. 5899
AMERICAN HOME PRODUCTS CORPORATION,	]	
Defendant.	]	

Elmer J. Scott, Attorney at law, Worland, Wyoming,Herbert R. Bennett and Keith Ferguson, Attorneys at law, Fort Dodge, Iowa, for Plaintiffs; Hirst, Applegate & Dray by Byron Hirst, Attorney at law, Cheyenne,Wyoming, and Lewis Perkiss, Attorney at law, New York, New York, for Defendant.

MEMORANDUM OPINION

WINNER, Judge

This memorandum opinion contains the

findings of fact and conclusions of law required by Rule 52. The citizenship of the parties is diverse, and the amount in controversy exceeds $10,000, exclusive of interest and costs. The Court has jurisdiction under 28 U.S.C. §1332. Trial of the case has been bifurcated to first determine the question of liability, and, if liability be found, damages are to be ascertained in later trial. There were sharp conflicts in the testimony, but I find the facts to be as hereinafter set forth.

William and Maxine Haste are Wyoming cattle ranchers. They purchased 45 head of cattle with calves from an area which, unknown to them, was a region in which the dread disease, anaplasmosis, was prevalent, and, in 1970, they lost 28 head of cattle to that disease. Plaintiffs feared contamination and loss of much of their herd, although it is probable that once they suffered their initial loss, future losses would have been small.

Defendant is a leading manufacturer of vaccines and medicines for animals. It advertises widely among the owners of domestic animals as well as among veterinarians. It is a company which is highly respected, and which was known to and was trusted, and relied upon, by plaintiffs. Among the products developed and promoted by defendant is the vaccine, Anaplaz, which is seemingly the only vaccine

offered for the control of anaplasmosis. Plaintiffs first learned of Anaplaz from defendant's advertising which was directed to the general public.

As to the disease anaplasmosis, the United States Department of Agriculture has reported:

> "Anaplasmosis is one of the most costly diseases of beef cattle in this country. Some 50,000 to 100,000 cattle die of anaplasmosis each year. Death loss where the disease is introduced into a herd will average 10 percent and may reach as high as 50 percent. Annual loss is estimated at $100 million due to livestock deaths and decrease in beef and milk production."

Anaplaz is extremely effective in controlling anaplasmosis, and indeed, it seems to have controlled the disease in the Haste herd. Plaintiffs make no complaint as to the effectiveness of Anaplaz in controlling anaplasmosis. What they do complain about is the alleged side effects of Anaplaz. They say that the vaccine caused neonatal isoerythrolysis, which, happily, the parties and persons in the industry customarily refer to as "NI", and that is the way I shall refer to the disease throughout this opinion. An accepted definition of NI which plaintiffs say caused

the loss of part of their calf crop as a proximate result of the Anaplaz vaccinations is:

> "The presence of a pathological condition in neonatal calves, resulting in anemia, icterus, illness or death due to the presence of red cell antibodies which attach to and destroy the calf's red cells or interfere with their functioning."

It has been theorized that this complicated blood disease is caused by the incompatibility of the antibodies received from the females and the antigens received from the males in the red blood cells of the infant animal. Although the disease was recognized and known to exist in other species, NI was first reported in bovines in about 1968, and, to this day, not a great deal is known about the disease. However, it cannot be disputed that some of plaintiffs' calves died from NI after their herd was vaccinated with Anaplaz.

At this point, I digress to briefly trace the developmental history of Anaplaz. It was first produced in 1965, and it has been licensed by the United States Department of Agriculture in accordance with the provisions of 21 U.S.C. § 151, et seq and regulations issued by the Department of Agriculture, 9 C.F.R. 101, et seq. In fact a series of licenses have been issued by the Department of

Agriculture, and all contain language, "Distribution of this product shall be restricted to veterinarians," or "This product shall be restricted to use under the direction of a veterinarian." The containers of the Anaplaz purchased by plaintiffs bore the Department of Agriculture approved label:

> "Do not use until insert leaflet has been read, understood, and explained to the owner.
>
> "Warning: Restricted by the U.S. Department of Agriculture to use by or on the order of a licensed veterinarian."

The enclosed leaflet, which plaintiffs read hastily before vaccinating their cattle says:

> "Anaplasmosis Vaccine
> "Inactivated - Desiccated
> Anaplaz
>
> "For use in healthy cattle as an aid in prevention of clinical symptoms of bovine anaplasmosis caused by Anaplasma marginale.
>
> "No U.S. standard of potency. This product has been potency tested as specified in Fort Dodge Laboratories production manual.

> "Composition. Anaplaz is composed of A. marginale organisms. It is concentrated, inactivated and lyophilized. A specially prepared adjuvant is used for reconstitution to facilitate absorption of the vaccine at a proper rate so as to elicit the maximum antigenic response.
>
> "General Information. It is important to vaccinate cattle twice, at not less than four-week intervals, with the second injection preceding the beginning of the insect vector season by at least two weeks. Preliminary results indicate that complement fixation antibodies may be expected to persist in vaccinated cattle for 1 to 4 months after the second injection. A 2 cc. booster dose should be given annually or at any time when epidemic conditions exist or exposure is anticipated.
>
> "Laboratory and field studies indicate that two injections at not less than four-week intervals prevent clinical illness and death from anaplasmosis during subsequent vector season. The 'carrier' state may occur in vaccinated cattle upon subsequent exposure to infection. However, clinical symptoms of anaplas-

mosis, erythrocyte infection and anemia in such cattle is absent or minimal.

"Administration and Dosage. Sterile adjuvant diluent is supplied with each vial of Anaplaz. To restore to a liquid state, aseptically withdraw the tneire diluent contents into a clean sterile syringe and inject directly in the vialof vaccine. Shake until thoroughly dissolved. Inject 2 cc. of the reconstituted vaccine subcutaneously in the neck or behind the shoulder using a separate sterile needle for each individual animal. Repeat in not less than 4 weeks. To avoid economic loss from injection site trimout, or possible unwholesomeness of meat, do not slaughter vaccinates for food within 60 days.

"Caution. Store in dark at 35° to 45 ° F. Shake vigorously after reconstitution to effect complete solution. Use entire contents without delay after restoration. In case of anaplylactoid reaction administer epinephrine.

"Warning. Restricted by the U.S. Department of Agriculture to use by

or on the order of a licensed veterinarian.

"It has been reported that the use of Anaplaz may be associated in some manner with the occurence of neonatal isoerythrolysis (NI) in offspring of vaccinates. Anaplaz may be a contributing factor to NI, although other mechanisms for this condition are known to exist in other species. NI is an anemic syndrome of healthy newborn calves. The onset of this disease is sudden after the intake of colostrum, with death of the affected calves usually occurring by the fourth day.

"Field evidence suggests the vaccine of brood cows with Anaplaz can be a calculated risk and the protective benefits of vaccination should be weighed against the posible risk of neonatal isoerythrolysis, which has been reported in 44 herds resulting in the death of 240calves. These losses occurred late in 1968 and the 1969 season with the vaccine having been used since 1965. Although not proven, it is theorized that Anaplaz may sensitize the dam against erythrocyte antigens the offspring inherits from the sire. Evidence

suggests a breed predisposition exists with 75% of the known cases existing in Charolais or Charolais crosses.

"If NI is suspected or observed, affected calves should be removed from the dam, placed on a nurse cow and given blood transfusions and corticosteroid therapy. Additional supportive treatment should be used as indicated. As an aid in the prevention of neonatal isoerythrolysis in offspring of vaccinates, it may be advisable to withhold colostrum from newborns for the first 36 hours. During this time newborns should be placed on a non-related nurse cow or given synthetic milk. After the 36-hour withholding period calves may nurse their dams providing have been milked out during this time. This colustrum withholding procedure is not withou its risks as the calf is thus deprived of the disease protective benefits of colostrum.

"Consult your veterinarian for further advise."

[So reads the fine print package insert defendant says gives crystal clear warning to a Wyoming cowman

as to the hazards which may result from Anaplaz vaccinations.]

Defendant urges that Anaplaz is a prescription drug, and that it is entitled to any benefits it can derive from cases holding manufacturers harmless where the product involved is a prescription drug. Defendant points to a letter from Dr. Garlick,(1) and in its brief defendant says:

> "It is eminently clear from Dr. Garlick's letter and from the scientific, expert testimony adduced at the trial, that Anaplaz is a very complicated and complex product the understanding of which requires special training, knowledge and expertise that is beyond the layman. In the hands of the public this vaccine would be extremely unsafe with a great potentiality for harm."

. . . . . .

(1) Dr. Garlick is Chairman of the Department of Laboratory Medicine at the Medical University of South Carolina. He was Chief Staff Veterinarian, Viral and Parasitic Cattle Disease, Animal Disease Eradication Division, Agricultural Research Service, U.S. Department of Agriculture in 1965 at the time licensing of Anaplaz was considered.

Thus, defendant's argument that Anaplaz is to be regarded as a prescription drug is not an unmixed blessing to it in light of its sales efforts aimed directly at cattlemen which will be discussed presently. I have already mentioned that plaintiffs first learned about Anaplaz from an advertisement in one of the more than 40 publications in which defendant advertised and promoted the product.(2) A review of the advertising addressed to cattlemen and the public at large demonstrates that defendant did not even hint at any side effects of Anaplaz and that the sales literature would lead any cattleman to think that Anaplaz was a vaccine which could be used without any risk whatsoever.

Understandably, and justifiably, the advertising is laudatory of Anaplaz, but, in addition to the broad commendatory language, published advertisements say, for example:

> "So vaccinations not only protects your cow herd, but your profits from two calf crops as well. With ease, safety, and economy."
>
> "'Anaplaz' is an inactivated vaccine, incapable of producing disease. It has

. . . . . .

(2) Answers to plaintiff's interrogatory No. 40.

> been scientifically researched, developed and tested by controlled procedures under both laboratory and actual field conditions. Extensive trials have been conducted in herds on widely separated farms and ranches."

The "Dear Doctor" letters recognized the risk of NI, but the material directed to the ultimate purchaser gave no clue that there was any risk. The advertising literature did not mention a release by the United States Department of Agriculture dated December 29, 1969, which said, inter alia:

> "Vaccinating brood cows with anaplasmosis vaccine sometimes may cause fatal side-effects in calves, the U.S. Department of Agriculture cautioned today.
>
> "Two components of USDA's Agricultural Research Service, the Veterinary Biologics Division and the Animal Health Division, have just completed a field investigation of 23 herds in Texas, Louisiana, and Georgia, in which early calf losses were recently reported. The Federal investigators found evidence in about half of these herds that isohemolytic anemia (nonfunctioning of red blood cells caused by immune reaction) was involved, with anaplasmosis vaccine as a possible contributing factor. In

these herds, calf loss averaged about 10 percent, investigators say. The ARS men confirmed earlier reports that most of the affected calves were Charolais or Charolais crosses, although they noted a few cases in other breeds."

With their cattle having anaplasmosis, and having become interested in Anaplaz through defendant's advertising, in the spring of 1971, plaintiffs consulted Dr. Virgil Humphreys, a veterinarian in Worland, Wyoming, and they asked him about Anaplaz. He advised them that the risks were minimal; that any side effects typically showed up in Charolais cattle, but cattle, but that he vaccinated his own Charolais with Anaplaz. He recommended that plaintiffs vaccinate with Anaplaz, and he gave them a throw-away type brochure on Anaplaz supplied by defendant [Exhibit 23 (1).] This brochure, which plaintiffs studied much more carefully than they did the package insert contained in their purchased packages of Anaplaz, praises the product and urges its use as a completely safe vaccine. The brochure stresses the ready availability of Anaplaz. It says:

"Mostly, today's losses are needless -- because they can be effectively

prevented by Anaplaz vaccine, readily available from your veterinarian."

Plaintiffs were assured in the brochure that, "Vaccination with Anaplaz has met 'trial by fire' in five years of field use," and that, "With coordinated effort, a successful breakthrough was finally made, resulting in a safe, practical and effective vaccine." The brochure told plaintiffs that, "Five years of Anaplaz field use has shown there's no longer any reason for running the risks or suffering the ravages of anaplasomsis." They were not told that one calculated risk which they might want to consider as a reason not to use Anaplaz was the risk of NI.

It was not until October, 1971, that plaintiffs went to Dr. Roberts, another veterinarian, who did not recommend the use of Anaplaz, but he did not mention any risk of NI. The evidence is sharply conflicting on the extent and detail of the advice given plaintiffs by Dr. Roberts, but I find that it was minimal. In any event, he had no reluctance in or-ordering the vaccine for plaintiffs [at a tidy profit to himself] when plaintiffs again visited him a few weeks later, and he delivered the vaccine to plaintiffs

after it arrived. I accept plaintiffs' testimony as to the extent of Dr. Roberts' warning, and I do not think that his warning was of a nature to place a reasonable cattleman on notice of realistic risk from use of anaplaz. Plaintiffs purchased the required "booster shot" of Anaplaz from a third veterinarian, Dr. Lester, and he gave plaintiffs no warning of risk of NI. The vaccinations were administered by plaintiffs, and the final "booster shot" was given in January, 1973. Plaintiffs charge that from 20 to 40 of their cattle came down with NI and died as a proximate result of the Anaplaz vaccinations.

The opinion testimony is diametric as to causation. The product is new, and perhaps further scientific study and research will prove defendant's experts to be right, but as the trier of fact, and based upon the expert testimony so saying, I find that the Anaplaz vaccinations of plaintiffs' herd was the proximate cause of the NI later discovered in those cattle.(3) This finding of

. . . . . .

(3) In so finding, I am not unaware of evidence tending to show that one cow diagnosed as having NI was not vaccinated with Anaplaz, but I think

proximate cause is, of course, essential if plaintiffs are to recover on any of their theories which are, strict liability, negligence, breach of warranty and [by post trial amendment] violation of federal statute.

I start with mention of plaintiffs' claim for strict liability as defined by Sec. 402-A of the Restatement of Torts. In this rapidly expanding field, it appears that more than 40 states have incorporated the principles of Sec. 402-A of the Restatement of Torts into their law, but Wyoming has not. Within the past year, an invitation to accept as part of Wyoming law the strict liability doctrine of Sec. 401-A was rejected by the Wyoming Supreme Court. Maxted v. Pacific Car & Foundry Company (1974) 527 P. 2d 832. As a visiting judge, I shy away from predicting the future course of Wyoming law, and I think that I can do so because I generally accept the statement in defendant's brief:

. . . . . .

> that the preponderance of the evidence shows the causal connection between Anaplaz and NI. That connection is surely not established beyond a reasonable doubt, but I think that the civil case test of preponderance of the evidence is met.

"To recover on either strict liability, negligence or breach of implied warranty, the Plaintiffs must prove that Anaplaz caused the alleged damages [I have so found] and that the vaccine was defective in that it was either impure or lacked an appropriate warning. There is no substantive legal distinction to be made among the three theories as related to this action."

As was said in Davis v. Wyeth Laboratories, Inc. (1968) 9 Cir. 399 F. 2d 121: (4)

"We find no error in the District Court's choice to present the case to the jury on warranty rather than on strict liability in tort. The law as emerging is tending toward the latter treatment but under either approach the elements remain the same. The difference is largely one of terminology."

. . . . . .

(4) Judge Merrill's discussion of balancing of interests and the duty for full warning in drug cases is deserving of careful study.

Moreover, for purposes of resolution of this case, I accept defendant's arguments that Anaplaz and its sale should be treated as the sale of a prescription drug, albeit the record is short a few elements of proof of a true prescription drug. I accept this argument with the caveat that when defendant advertises directly to the cattleman and and when the cattleman is the object of a concentrated sales pitch, there is a duty to warn the rancher of potential risks in the advertising and sales material which promote the sale of the product. It won't do to entice the cattleman to purchase Anaplaz with glowing sales literature and then to warn him with a package insert after he has spent several hundred dollars on the purchase. It is true that defendant sent out some "Dear Doctor" letters, and that Anaplaz could be purchased only through veterinarians who presumably received the letters. My thinking as to the effectiveness of those letters are expressed by Chief Judge Nichol in Yarrow v. Sterling Drug, Inc. (1967) D.C. S.D. 263 F. Supp. 159, and by Judge Becker in his affirmance of the case, Sterling Drug, Inc. v. Yarrow (1969) 8 Cir. 408 F. 2d 978. I think that based on the state of scientific knowledge when plaintiffs purchased the Anaplaz, and had plaintiffs not been

pre-sold on its use by the advertising literature, the warning is borderline, but it might be sufficient. I say this even though I think that defendant had access to much more knowledge and literature than it is willing to admit which suggested that Anaplaz caused NI. Illustrative, are articles by Dr. Richard Dennis and Mark F. Young, as well as an Arkansas State Veterinarian publication, and, of course, the Department of Agriculture release. The "Dear Doctor" letters play down the relationship between Anaplaz and NI, and the literature and most particularly the package insert says that, "Evidence suggests a breed disposition exists with 75% of the known cases existing in Charolais or Charolais crosses." [Plaintiffs were raising Santa Gertrudis.] At best, the package insert warning is skimpy even for a drug sold as a true prescription drug not advertised directly to the public. With the sales job defendant did on the cattlemen who were the ultimate purchasers, the warning is entirely inadequate, and defendant is liable for failure to adequately warn of the danger of NI. It is to be remembered that, as said in defendant's brief, Anaplaz is a product which "in the hands of the public ... would be extremely unsafe with a great potential for harm." I think that the direct sales effort

[even though the product was channeled through veterinarians] imposed on defendant a duty to warn the ultimate consumer before he spent his money on the purchase. Defendant's duty was to warn fully and fairly of risks likely to be encountered as shown by all of the scientific knowledge -- not just that shown by knowledge culled, slanted and carefully selected by defendant. Imposing such a duty is not unfair. A manufacturer has a business decision to make in circumstances such as these. It can merchandise only through trained doctors or veterinarians without direct sales appeal to the public. Or, in the intertests of increasing sales, the manufacturer can argue the merits of its product to the public, thus creating a public demand for purchase through the merchandising chain of veterinarians or doctors. If the manufactuer, in the exercise of its business judgment, elects the latter course, it picks up a duty to warn the public in all advertising literature of any risks. Here we have a proprietary vaccine; not something compounded by a pharmicist on prescription. We have a proprietary vaccine vigorously promoted by defendant with sales efforts concentrated on the purchasing public. Liability cannot be avoided under these circumstances by tucking a warning in the

age to be seen for the first time after the order is placed and delivery of the order is made.

Faced with almost 300 pages of briefs, I make no effort to discuss the countless cases cited and quoted by counsel. This is not to say that the cases do not bear on the issued and the problems. They do, but time and space do not permit an analysis or discussion of more than a select few of the authorities.

Plaintiffs seek recovery on express and implied warranties of fitness. Wyoming has adopted the Uniform Commercial Code, and privity is not required to permit recovery on a warranty theory. See, Wyoming statutes, 34-2-318. Plaintiffs here relied on defendant and relied on the efficaciousness of Anaplaz to treat anaplasmosis without harmful side effects. Although I have found that defendant knew or should have known of the risks involved in the use of Anaplaz, as is said in 63 Am. Jur. 2d, Products Liability _97:

> "A general warranty is deemed to cover all defects within its scope whether known to the manufacturer or seller or not, and this is true regardless of whether the warranty

> is express or implied. In other words, the seller's knowledge of the falsity of the warranty is not an essential element of his liability for breach of the warranty."

In Colorado Serum Company v. Arp (1972) 504 P. 2d 801, the Wyoming Supreme Court upheld an award for the death of pigs resulting from their vaccination with hog cholera manufactured by defendant and purchased by plaintiff through ordinary commercial channels. The elements required for recovery on a warranty theory were said to be:

> "We agree with defendant in its statement in the brief that plaintiffs tried their case on the theory of breached express and implied warranties; and we think they were entitled to elect so to do under §§ 34-2-213 and 34-2-318, W.S. 1957, 1971 Cum. Supp. Perhaps the pivotal argument of defendants in the appeal is that plaintiffs in order to prevail must show first that there was a defective product, second how it was defective, and third that the defendant was responsible for the defect under Wyoming law. In so arguing counsel is insistent that the absence of the allegedly defec-

ive product does not excuse the necessity of proving the defect and its nature. True, the above mentioned three factors must be proved; but there would seem to be no requirement that the allegedly defective product must be presented in evidence and shown by analysis to be ipso facto defective. Such proof is permissible by circumstantial evidence. . . . . .

"In the present litigation although the evidence was circumstantial, it was sufficient to justify the court's holding that:

"'The preponderance of evidence proves that one or both of the bottles of Colorado Serum Company's Hog Cholera Vaccine which plaintiffs purchased on august 3, 1966, was defective as a result of manufacture in that one or both of the bottles contained live Hog Cholea Virus; that the defect in the product constituted a breach of defendant's implied warranty of merchantability, implied warranty of fitness for a particular purpose, and its express warranty that the product was incapable of inducing disease; and * * * was the direct and proximate

cause of plaintiff's loss of their swine herd and of their subseuent damage.'"

I have found no very helpful Wyoming case on the duty of a manufacturer-seller to warn a prospective purchaser concerning a product which "in the hands of the public . . . would be extremely unsafe with a great potential for harm," but a general discussion of the duty to warn appears in 63 Am. Jur. 2d, Products Liability, §42 et seq. More importantly, in connection with my finding and conclusion that the duty to warn increases with the manufacturer's direct sales efforts directed to the public, two cases quoted and relied upon by defendant are to be noted. Defendant argues that the cases are exculpatory. I think that they are inculpatory under the facts of this case. Both cases had to do with Sabin oral polio vaccine and its general beneficial results, and both held Wyeth Laboratories liable.

The first is Davis v. Wyeth laboratories, Inc. (1968) 9 Cir. 399 F. 2d 121. The case should be read in its entirety for its full impact, but, briefly, the Surgeon General recommended the use of the vaccine and said that risk was "less than 1 case per million doses."

Warnings were given to the medical societies of this small risk, but at West Yellowstone where plaintiff obtained the oral vaccine, it was provided by a pharmacist. Defendant was being paid only 25¢ per dose, yet it was held liable for failure to direct a warning to the one in a million ultimate consumer who contracted polio from the oral vaccine. the case holds:

> "We conclude that the facts of this case imposed on the manufacturer a duty to warn the consumer (or make adequate provision for his being warned) as to the risks involved, and that failure to meet this duty rendered the drug unfit in the sense that it was thereby rendered unreasonably dangerous. Strict liability, then, attached to its sale in absence of warning.
>
> "Appellee contends that its duty to warn was met by Franklin's disclosures to the medical society. It points out that its only direct sale of vaccine was to the medical society and that it was the society's judgment and not appellee's to proceed with the clinics.

> "Ordinarily in the case of prescription drugs warning to the prescribing physician is sufficient. In such cases the choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities. Further it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning. A warning to the medical profession is in such cases the only effective means by which a warning could help the patient.
>
> "Here, however, although the drug was denominated a prescription drug it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing by a physician or the risks involved. In such cases (as in the case of over-the-counter sales of nonprescription drugs) warning by the manufacturer to its immediate purchaser will not suffice. The decision (that on balance and in the public interest the personal risk to the individual was worth taking) may well have been

that of the medical society and not that of appellee. But just as the responsibility for choice is not one that the manufacturer can assume for all comers, neither is it one that he can allow his immediate purchaser to assume. In such cases, then, it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning. Here appellee knew that warnings were not reaching the consumer. Apellee had taken an active part in setting up the mass immunization clinic program for the society and well knew that the program did not make any such provision, either in advertising prior to the clinics or at the clinics themselves. On the contrary, it attempted to assure all members of the community that they should take the vaccine.

"We conclude that appellee did not meet its duty to warn.

"This duty does not impose an unreasonable burden on the manufacturer. When drugs are sold over the counter to all comers warnings normally can

be given by proper labeling. Such method of giving warning was not available here, since the vaccine came in bottles never seen by the consumer. But other means of communication such as advertisements, posters, releases to be read and signed by recipients of the vaccine, or oral warnings were clearly available and could easily have been undertaken or prescribed by appellee.

"For these reasons we hold that it was error to fail to instruct the jury, either in warranty or in tort, that appellee was strictly liable if its drug caused appellant to contract polio and if appellant's taking of the drug was without knowledge of risk."

Reyes v. Wyeth Laboratories (1974) 5 Cir. 498 F. 2d 1264, is an able opinion by Judge Wisdom which follows Davis, supra. Reyes was solely a Sec. 402-A case, but the reasoning is applicable whether or not Wyoming decides to go along with the Restatement of Torts on strict liability. The court recognized the prescription drug exception to liability, commented that Sabin oral vaccine is licensed for sale only as a prescription drug, but noted that it was not administered as such.

It was said:

> "Thus, as in the case of patent drugs sold over the counter without prescription, the manufacturer of a prescription drug who knows or has reason to know that it will not be dispensed as such a drug must provide the consumer with adequate information so that he can balance the risks and benefits of a given medication himself. Moreover, just as the manufacturer cannot make this choice for its ultimate consumers, it cannot allow its imediate purchaser to choose for them. In sum, then, the manufacturer is required to warn the ultimate consumer, or to see that he is warned. . . .
>
> "Wyeth knew or had reason to know that the vaccine would not be administered as a prescription drug, and therefore was required to warn foreseeable users, or see that the Texas Department of Health warned them."

Here, too, defendant knew or had reason to know that Anaplaz would not be administered as a prescription drug. It had a duty to warn foreseeable users, and that duty was for a clear, explicit warning in the solicitations leading to the sale -- not just in a package

insert after the solicited sale had been accomplished.

Curiously, in the very long briefs, neither party makes mention of the cases which worry me the most in light of the evidence that only a very small percentage of cattle vaccinated with Anaplaz become afflicted with NI. Since the cases are from the Tenth Circuit, they will be discussed.

Merrill v. Beaute Vues Corporation (1956) 10 Cir. 235 F. 2d 893, is a case in which plaintiff claimed injury from the use of a permanent wave product. After jury verdict in plaintiff's favor, the court entered judgement for defendant under its finding that, "even if plaintiff was injured by the use of defendant's product, she was not a member of a class expected to be affected by the use of the product and her injury constituted an isolated instance of injury to an unusually susceptible individual." The Court of Appeals affirmed. The Court stressed that the only evidence of the harmful effect of the solution was a 10-year old article by a doctor who was not called as a witness, and it said:

> "Whether Dr. Cotter would have the same opinions and fears now that he did almost ten years ago, we do not know for he was not called as a witness. If this product is inherenty

dangerous and injurious to the millions who now use it, surely some qualified witness would have been present to so testify and reliance on a magazine article published almost ten years before to establish that fact would not have been necessary."

Judge Pickett's opinion continues:

"Although there was no direct evidence tending to show that the plaintff was allergic to defendants' product or that her injury constituted an isolated injury to an unusually susceptible individual, the undusiputed evidence is that with the exception of two cases referred to in the Robson-Cameron article, the injury to plaintiff's optic nerve is the only one reported out of five hundred milion users of the product. This in itself is sufficient to sustain the court's finding on this subject. We are satisfied that considering all the facts and circumstances the issue was raised and the findings necessary. We therefore have the question as to whether a manufacturer who places a product on the market, knowing that on this subject. We are satisfied

that considering all the facts and circumstances the issue was raised and the findings necessary. We therefore have the question as to whether a manufacturer who places a product on the market, knowing that some unknown few, not in an identifiable class which could be effectively warned, may suffer allergic reactions or other isolated injuries not common to the ordinary or normal person, must respond in damages. Although there is authority to the contrary, we think the prevailing and better rule is that the injured persons in such cases cannot prevail. The reason generally given for the rule is that the injury is caused by allergy or the unusual susceptibility of the person and not the product. The essence of these decisions is that a reasonable person could not foresee the purchaser's condition and could not anticipate the harmful consequences. In the case at bar, as in similar cases, the plaintiff herself did not know that a usually harmless product could cause injury to her optic nerve. Until after the filing of the complaing, the defendants had no knowledge of like injuries to

others, and then only two were reported. Under the circumstances, a warning would have been wholly ineffective.

. . . . . .

"Neither do we think that the defendants are liable to plaintiff on an implied or express warranty. Warranties do not extend to injuries caused by peculiar idiosyncrasies or physical condition of a user which are not reasonably foreseeable. The rule as to negligence insuch cases applies to warranties."

Judge Murrah concurred specially on the ground that plaintiff in Beaute Vues was an isolated individual, not a member of a class. He said:

"But where the proof shows that 'some', or even a 'small proportion', will be injuriously affected by the use of a manufacturer's product, some courts have recognized the duty to wran of the known or imputed dangers at the risk of liability. See Bianchi v. Denholm & McKay Co., 302 Mass. 469, 19 N.E. 2d 697, 121 A.L.R. 460; Zirpola v. Adam Hat Stores, 122 N.J.L. 21, 4 A. 2d

73; Reynolds v. Sun Ray Drug Co., 135 N.J.L. 475, 52 A. 2d 666.

"The difficulty lies in the failure of the law to recognize the allergic or unusually susceptible plaintiff as a class of people to whom a manufacturer owes a legal duty to warn a potential dangers. Once the allergic plaintiff is rcogniozed as one of a class of 'some' people, the consequent legal duty becomes too plain for doubt. Science and medicine have now recognized the allergic and hyper-sensitive as a definite class of people, presenting physicological and biochemical problems arising out of the use of and contact with the products of advanced chemistry. See Cooke, Allergy in Theory and Practice; Feinberg, Allergy in Practice. If the law is to keep apace of the socialistic problems wrought by science and technology, it is high time for the courts to also recognize the allergic or unusually susceptible as members of a legally indentifiable class, to whom the law will extend its protection in warranty and in tort, and not as isolated individuals of whom the law takes no account."

Distinguishing Beaute Vues from this case are these facts:

(1) The live testimony missing in Beaute Vues is here present.

(2) Factual information available to American Home Products gave it far more warning of danger than did the information available to Beaute Vues.

(3) There is an identifiable class of cattle which get NI from Anaplaz -- the case does not involve an isolated individual cow.

(4) American Home Products admits that Anaplaz is a dangerous product in the hands of the public.

(5) American Home Products recognizes a duty to warn in its "Dear Doctor" letters, but it gave no warning to the consuming public.

In Ray v. J.C. Penney Company (1959) 10 Cir. 274 F. 2d 519, plaintiff had an allergic reaction to a pair of gloves purchased from Penney's. A jury verdict in defendant's favor was affirmed and the following instruction was approved:

> "The most serious question arises with respect to the court's instruction Number 6, in which the court

instructed the jury that,

> "'You are instructed that warranties do not extend to injuries caused by peculiar idiosyncrasies or physical condition of a user which are not reasonably foreseeable.
>
> "'The law requires a person to reasonably guard against probabilities, not possibilities, and one who sells a product on the market, knowing taht some unknown few, not in an identifiable class which could be effectively warned, may suffer allergic reactions or other isolated injuries not common to ordinary or normal persons, need not respond in damages.
>
> "'If you find that the plaintiff's injury was an isolated instance to an unusually susceptible individual then you must find for the defendant.'"

All except the first distinction applicable to Beaute Vues apply to Ray v. J.C. Penney Company, and, presumably, the jury found that Ray was an isolated individual.

Tayar v. Roux Laboratories, Inc. (1972) 10 Cir. reversed a trial court award to plaintiff for injuries sustained by her attributable to use of a hair rinse manufactured by defendant. Judge Barrett said:

> "The manufacturer of a product has a duty to warn consumers of potential dangers from the product when it knows or should know they exist. Roux alleges that no evidence was introduced which showed that it knew its products would injure the user or that any particular ingredients in the products were dangerous. Until Tayar's injuries, Roux believed that its rinse products were harmless.
>
> "Tayar alleges that Roux was negligent in not attaching warning labels to its products advising consumers to wear rubber gloves during application. There were no warning labels on the Roux products Tayar used when she was injured. There is no evidence indicating how many people were sensitive to the product who might be damaged by its use. Tayar's condition is the only incident of injury reported. The record is devoid of substantial evidence that Roux knew the dangerous character of its products prior to Tayar's injuries and complaint. It was not, accordingly, required to warn consumers until Tayar was injured.

> "Roux alleges that Tayar's injury was the result of an idiosyncratic allergic reaction which precludes recovery. Damages for injuries is denied when the use of a product is safe for the vast majority of consumers. Merrill v. Beaute Vues Corporation, 235 F. 2d 893 (10th Cir. 1956). When a manufacturer places a product on the market, knowing that a few, not in an identifiable class, may suffer allergic reactions not common to the normal person, the injured party cannot recover. Merrill v. Beaute Vues Corporation, supra. The rule is based on the proposition that an injury may be caused by an allergy or unusual susceptibility which the manufacturer cannot reasonably foresee in relation to the use of its product. The manufacturer is not, under these circumstances, liable for the purchaser's condition or obligated to anticipate the harmful consequences.
>
> 'Warranties do not extend to injuries caused by peculiar idiosyncracies or physical condition of a user which are not reasonably foreseeable. The rule as to negligence in such cases applies to warranties.' 235 F. 2d at 898.
>
> "See also Ray v. J. C. Penney Company, 274

F. 2d 519 (10th Cir. 1959).

. . . . . .

"Roux's rinse products were universally used and accepted as harmless. No evidence was introduced to show that anyone other than Tayar suffered an adverse reaction from the use of the products. She had an allergic or an idiosyncratic reaction which caused her to be unusually susceptible to agents which are normally safe for use by the public. In these circumstances the manufacturer is not liable for damages."

Although I concede that some of the language in Tayar, read out of context, may give some solace to defendant here, I think that the case is subject to the same distinctions to be aplied to the other two Tenth Circuit cases, and, most importantly, defendant here admits the dangerous nature of Anaplaz.

This leaves then as plaintiffs' only other claim their post trial claim of a right to recover for a violation of federal statute. This claim must rest on White v. Rose (1957) 10 Cir. 241 F. 2d 94. I admit that for 18 years I have thought that Judge Breitenstein's trial court opinion and Judge Hill's dissent in the case were right, and I plead guilty to any charge that my belief that the case is inapplicable

may be the result of still tender scar tissue resulting from my loss of the case. Nevertheless, I do not think that the federal statutes create what amounts to an insurer's liability as the majority in White v. Rose held was created by the Colorado statutes. For that reason, I conclude that plaintiffs cannot recover on their federal statutory claims.

I have considered, but I completely reject the defenses of contributory negligence and assumption of risk. My rejection of these defenses is on a factual basis, because I believe that under proper circumstances the defenses do apply,(5) but the proof fails to establish either defense in this case, from the facts I have found I think that there is no proof that plaintiffs did anything a reasonably prudent person would do, when prompted by considerations which ordinarily regulate the conduct of human affairs. I do not think that the proof establishes that plaintiffs failed to use ordinary care under the circumstances in the management of their

. . . . . .

(5) See, Murphy v. Petrolane-Wyoming Gas Service (1970) Wyo. 468 F. 2d 969, Continental Motors Corp. v. Joly (1971) Wyo. 483 P. 2d 244, and Parker v. Heasler Plumbing and Heating Co. (1964) Wyo. 388 P. 2d 516.

property and affairs. Certainly, they did not assume the risk, because they didn't know and understand the risk.

Lastly, I reject plaintiffs' claim for punitive damages. The proof does not justify the award of any such damages. Defendant did not intentionally cause injury to plaintiffs' cattle. Defendant's acts were not willful or wanton. Defendant was not guilty of malice. Defendant's motives were to benefit the cattle industry, and the overall results of the use of Anaplaz are extremely beneficial to that industry. The proof in this case does not even approach proof of bad faith on defendant's part. The case is purely and simply one in which it must be decided who is to bear the risk of loss under the unfortunate circumstances presented when, as I have held, an inadequate and improper warning was given by defendant. This is no case for the award of punitive damages -- the proof falls far short of the proof required to justify punishment of defendant. The case is one in which the questions of defendant's liability for compensatory damages is very, very close, and as review of the cases demonstrates, and especially a review of the Tenth Circuit cases, the question of defendant's liability for any damages is one on which reasonable minds may differ.

To summarize what I have held: I hazard no guess as to whether Wyoming will embrace the

doctrine of strict liability under Sec. 402-A of the Restatement of Torts; I hold that plaintiffs have established a right to recover damages under their alternative theories of breach of warranty and negligent failure to warn; that they have established no right to recover on the basis of violation of federal statute; that plaintiffs were not guilty of contributory negligence; that they did not assume the risk, and that the case is not one in which punitive damages should be awarded.

Counsel are requested to advise me by letter as to the time frame within which they wish to try the damage issue and of the estimated amount of time which should be reserved for that trial.

Dated at Denver, Colorado, this 13th day of June, 1975.

United States District Judge

21 U.S.C. § 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded -

Directions for use and warnings on label

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

Health-endangering when used as prescribed

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling

(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under subsection (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 371(e) of this title: Provided, That (A) except in extraordinary circumstances, no regulation issued under this subsection shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this subsection applicable to advertisements of prescription drugs, shall, with respect to the

matters specified in this subsection or covered by such regulations, be subject to the provisions of section 52 to 57 of Title 15. This subsection (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title.

21 U.S.C. § 353. Exemptions in case of drugs and devices - Regulations for goods to be processed, labeled, or repacked elsewhere

Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(b)(1) A drug intended for use by man which-

(A) is a habit-forming drug to which section 352(d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced

promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except subsections (a), (i) (2) and (3), (k), and (l) of said section, and the packaging requirements of subsections (g), (h), and (p) of said section, if the drug bears a label containing the name and address of the dispenser, the seial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

21 C.F.R. § 202.1(e) "True statement of information in brief summary relating to side effects, contraindications, and effectiveness:

(1) When required. All advertisements for any prescription drug ("prescribtion drug" as used in this section means drugs defined in Section 503(b)(1) of the act and § 201.105, applicable to drugs for use by man and veterinary drugs, respectively), except advertisements described in subparagraph (c)(2) of this section shall present a true statement of information in brief summary relating to side effects, contraindications (when used in this section "side effects, contraindications" include side efects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.) and effectiveness. Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadest presentation shall contain a brief summary of all necessary information related to side effects and contraindications.

(2) Exempt advertisements. The following advertisements are exempt from the requirements of paragraph (e)(1) of this section under the conditions specified.

(i) Reminder advertisements. Reminder advertisements if they contain only the proprietary or trade name of a drug (which necessitates declaring the established name, if any, and furnishing the formula showing quantitavely each ingredient of the drug to the extent required for labels) and, information relating to dosage form, quantity of package contents, price, the name and address of the manufacturer, packer, or distributor or other written, printed, or graphic matter containing no representation or suggestion relating to the advertised drug: Provided, however, That if the Commissioner finds that there is evidence of significant incidence of fatalities or serious damage associated with the use of a particular prescription drug, he may notify the manufacturer, packer, or distributor of the drug by mail that this exemption does not apply to such drug by reason of such finding: And provided, however, That reminder advertisements are not permitted for a drug for which an announcement has been published pursuant to review of the labeling claims for the drug by the National Academy of Sciences National Research Council, Drug Efficacy Study Group, and for which no claim has been evaluated as higher than "possibly effective". If the Commis-

sioner finds the circumstances are such that a reminder advertisement may be misleading to prescribers of drugs subject to NAS-NRC evaluation such advertisements will not be allowed and the manufacturer, packer, or distributor will be notified either in the publication of the conclusions on the effectiveness of the drug or by letter.

(ii) Advertisements of bulk-sale drugs. Advertisements of bulk-same drugs that promote sale of the drug in bulk packages in accordance with the practice of the trade solely to be processed, manufactured, labeled, or repackaged in substantial quantities and that contain no claims for the therapeutic safety or effectiveness of the drug.

(iii) Advertisements of prescription-compounding drugs. Advertisements of prescription-compunding drugs that promote sale of a drug for use as a prescription chemical or other compound for use by registered pharmacists in compounding prescriptions if the drug otherwise complies with the conditions for the labeling exemption contained in § 201.120 and the advertisement contains no claims for the therapeutic safety of effectiveness of the drug."

21 CFR § 202.1(e)(3) "Scope of information to be included; applicability to the entire advertisement.

(i) The requirement of a true statement of information relating to side effects, contraindications, and effectiveness applies to the entire advertisement. Untrue or misleading information in any part of the advertisement will not be corrected by the inclusion in another distinct part of the advertisement of brief statement containing true information relating to side effects, contraindications, and effectiveness of the drug. If any part or theme of the advertisement would make the advertisement false or misleading by reason of the omission of appropriate qualification or pertinent information, that part or theme shall include the appropriate qualification or pertinent information, which may be concise if it is supplemented by a prominent reference on each page to the presence and location elsewhere in the advertisement of a more complete discussion of such qualification or information."

21 CFR § 202.1(e)(3)(iii)

"The information relating to side effects and contraindications shall disclose each specific side effect and contraindication which include side effects, warnings, precautions, and contraindications and include any such information under such headings and cautions, special considerations, important notes, etc.; subparagraph (e)(1) of this section) contained in required, approved, or permitted labeling for the advertised drug dosage form(s); Provided However;

(a) The side effects and contraindications disclosed may be limited to those pertinent to the indications for which the drug is recommended or suggested in the advertisement to the extent that such limited disclosure has previously been approved or permitted in drug labeling conforming to the provisions of §§ 201.-100 or 201.105; and

21 CFR § 202.1(e)(5)

"True statement of information. An advertisement does not satisfy the requirement that it present a 'true statement' of information in brief summary relating to side effects, contraindications, and effectiveness if:

(i) It is false or misleading with respect to side effects, contraindications, or effectiveness; or

(ii) It fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug in that the information relating to effectiveness is presented in greater scope, depth, or detail than is required by Section 502(n) of the act and this information is not fairly balanced by a presentation of a summary of true information relating to side effects and contraindications of the drug; Provided, however, That no advertisement shall be considered to be in violation of this section if the presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness or safety.

(iii) It fails to reveal facts material in the light of its representations or material

with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement."

"Advertisements that are false, lacking in fair balance, or otherwise misleading. An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of Section 502(n) of the act, among other reasons, if it:

(i) Contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients (as used in this section "patients" means humans and in the case of veterinary drugs, other animals), safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience (as described in paragraph (e)(4)(iii)(b) and (c) of this section) whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

(iii) Contains favorable inforamtion or opinions about a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information,

or contains literature references or quotations that are significantly more favorable to the drug than has been demonstrated by substantial evidence or substantial clinical experience.

(iv) Contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective--presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.

(v) Presents information from a study in a way that implies that the study represents larger or more general experence with the drug than it actually does.

(xviii) uses headline, subheadline, or pictoral or other graphic matter in a way that is misleading.

Provided, however, That any provision of this paragraph shall be waived with respect to a specified advertisement as set forth in a written communication from the Food and Drug Administration on a petition for such a waiver from a person who would be adversely affected by the enforcement of such provision on the basis of a showing that the advertisement is

not false, lacking in fair balance, or otherwise violative of Section (502)(n) of the Act. A petition for such a waiver shall set forth clearly and concisely the petitioner's interest in the advertisement, the specific provision of this paragraph from which a waiver is sought, a complete copy of the advertisement, and a showing that the advertisement i not false, lacking in fair balance, or otherwise misleading, or otherwise violative of Section 502(n) of the act."

21 CFR § 202.1(e)(7)

"Advertisement that may be false, lacking in fair balance, or otherwise misleading. An advertisement may be false, lacking in fair balance, or otherwise misleading or otherwise violative of Section 502(n) of the act if it:

(i) Contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions.

(vii) Fails to provide sufficient emphasis for the information relating to side effects and contraindications, when such information is contained in a distinct part of an advertisement, because of repetition or other emphasis in that part of the advertisement of claims for effectiveness or safety of the drug.

(viii) Fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(xi) Fails to present on a page facing another page (or on another full page) of an advertisment on more than one page, information relating to side effects and contraindications when such information is in a distinct part of the advertisement.

(xii) Fails to include on each page or spread of an advertisement the information relating to side effects and contraindications or a prominent reference to its presence and location when it is presented as a distinct part of an advertisement.

21 CFR § 202.1(k)

"An advertisement issued or caused to be issued by the manufacturer, packer, or distributor of the drug promoted by the advertisement and which is not in compliance with Section 502(n) of the act and the applicable regulations thereunder shall cause stocks of such drug in possession of the person responsible for issuing or causing the issuance of the advertisement, and stocks of the drug distributed by such person and still in the channels of commerce, to be misbranded under Section 502(n) of the act.

(1)(1) Advertisements subect to Section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.

21 USC 201.105 Veterinary Drugs

A drug intended for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence, for which "adequate directions for use" cannot be prepared, shall be exempt from § 502(f)(1) of the act if all the following conditions are met.

(b) label

(1) "Caution: Federal law restricts to use by or on the order of a licensed veterinarian; and

(2) The recommended dosage

(3) Route of administration

(4) Quantity or proportion of each active ingredient

(5) If for other than oral use, the names of all inactive ingredients.

(6) An identifying lot or control number from which it is possible to determine the manufacturer's history.

(c)(1) Labeling on or within package bears adequate information for use including indications, hazards, contra-side effects

(d) Any labeling whether or not in packing - i.e. advertising.

(1) - including warnings.